

Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, IN 46268-1054

May 18, 2007 via electronic transmission

Mr. Joe Karkoski Senior Water Resources Engineer Central Valley Water Quality Control Board (CVWQCB) 11020 Sun Center Drive Rancho Cordova, CA 95670-6114

RE: Dow AgroSciences Comments Concerning Methodology for Derivation of Pesticide Water Quality Criteria for the Protection of Aquatic Life in the Sacramento and San Joaquin River Basins. Phase-II: Derivation of Chlorpyrifos Criteria

Dear Mr. Karkoski:

On behalf of Dow AgroSciences LLC (DAS), the primary registrant of chlorpyrifos, I submit the following comments on the December 2006 University of California-Davis Report entitled "Methodology for Derivation of Pesticide Water Quality Criteria (WQC) for the Protection of Aquatic Life in the Sacramento and San Joaquin River Basins: Phase-II: Chapter 4 Criteria Derivation Chlorpyrifos" by Dr. Patti TenBrook and Dr. Ronald Tjeerdema.

In Chapter 4 the proposed methodology is used to derive aquatic life criteria for chlorpyrifos. DAS notes that the authors excluded all of the Good Laboratory Practice (GLP) studies submitted to USEPA in their data analysis, claiming that the USEPA's review practice is unreliable and that the reports for the studies are not available for their review. They use this reasoning to exclude critical studies such as the *Daphnia magna* reproduction study and the fathead minnow full life cycle study from use in setting the chronic criterion.

The logic of the authors for excluding such data is faulty for the following reasons.

• Registrant studies are held to a very high standard of data quality by the need to follow standard study guidelines<sup>1</sup> and GLP requirements<sup>2</sup> independent of any

\_

<sup>&</sup>lt;sup>1</sup> 40 CFR Part 158 Data requirements for registration, § 158.20(c) Availability of related guidelines.

<sup>&</sup>lt;sup>2</sup> 40 CFR Part 160.

- subsequent review process. Therefore, the internal USEPA review process builds upon the guideline study protocols and the GLP documentation and auditing process, thus insuring a high baseline of study quality. The USEPA carefully reviews each study to judge acceptance or rejection based on meeting the protocol requirements and validation criteria. There are a total of 30 data points for aquatic species in the USEPA database<sup>3</sup> on chlorpyrifos that are rated "Core" studies by USEPA that have been ignored in this review.
- All of these data are available from USEPA or Cal EPA Department of Pesticide Registration.

The newly-developed final acute and chronic criteria for chlorpyrifos are lower than those established by the USEPA and the California Department of Fish and Game (CDFG). These differences are explained by the authors as due to different data sets used for the final calculations. In view of our previous comment regarding the exclusion of GLP studies submitted and accepted by the USEPA, DAS recommends a detailed comparison be developed showing the specific data sets used to calculate the USEPA, CDFG, and the proposed new criteria. Without this additional information, it is impossible to distinguish between data selection and algorithms used to manipulate the data to understand their relative influence on determining the final numbers.

Finally, the authors did not interpret the evidence from mesocosm, microcosm, and ecosystem studies appropriately. Instead of considering whether the protection level of the proposed criteria agreed with the results from these studies, the authors merely stated that the proposed criteria will be protective. Since the authors do not specify in the methodology their protection goal, such a comparison has little meaning. In contrast, when the population and community level information is evaluated and then compared to other data in a multiple lines of evidence approach, it is clear that the levels needed to protect aquatic communities are much closer to the USEPA acute criterion than the CDFG or proposed new criteria, and chronic effects with chlorpyrifos typically are not observed in aquatic ecosystems.<sup>4</sup>

Sincerely,

Nicholas N. Poletika, Ph.D.

Alicholas Mr. Poletila

Science Leader

Dow AgroSciences LLC

 $<sup>^3\ \</sup>underline{\text{http://www.epa.gov/oppefed1/general/databases description.htm\#ecotoxicity}}$ 

<sup>&</sup>lt;sup>4</sup> Giesy, J. P., K. R. Solomon, J. R. Coates, K. R. Dixon, J. M. Giddings and E. E. Kenega. 1999. Chlorpyrifos: Ecological Risk Assessment in North American Aquatic Environments. *Rev Environ Contam Toxicol* 160: 1-129.